The Global Harmonization Task Force:
An Introduction & Status Report

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Global Harmonization: What does it mean and what are the principal goals?

- Harmonization is a voluntary, multi-lateral consensus-building initiative to adjust regulations toward equivalence status
- Principal aims are to: (1) improve public health protection world-wide via common regulatory approaches; (2) promote technological innovation; (3) facilitate international trade
- If successful, will benefit regulators & industry by eliminating costly and duplicative processes and requirements

Global Harmonization Task Force: What is it?

- An international consortium formed in 1992, with representatives from regulatory bodies and industry in United States, Europe, Canada, Japan and Australia, with observer nations and organizations, e.g., WHO, ISO
- Mission is to “harmonize” medical device regulatory systems among participant countries and provide a model for world regulation
- Bulk of effort conducted via Study Groups

What areas are GHTF Study Groups presently concentrating on?

- SG 1 (Freeman - Belgium): Premarket Review/Technical Requirements
- SG 2 (Kessler - U.S.): Medical Device Vigilance & Post-Market Surveillance
- SG 3 (Trautman - U.S.): Quality System Requirements and Guidance
- SG 4 (Allen - U.K.): Auditing

Fundamental Challenge: Understanding & Reconciling Different Regulatory Approaches

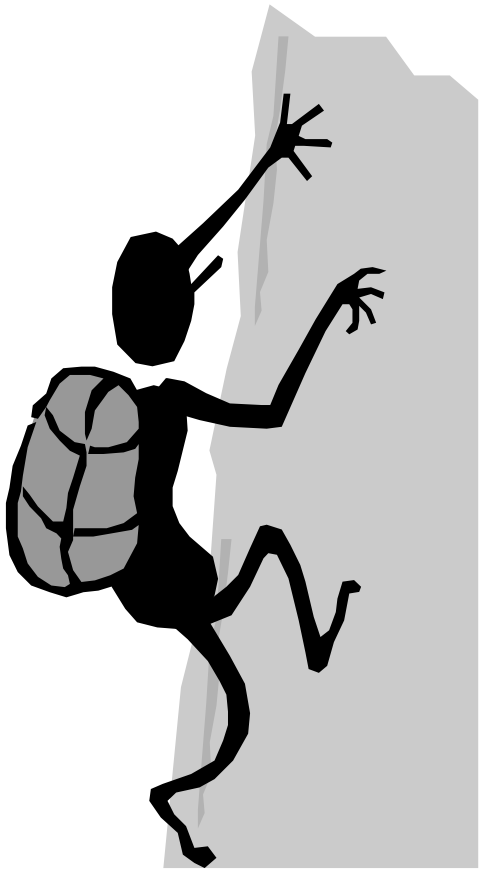
U.S. vs. EU

- Low Risk:
  - substantial equivalence; self certification
- Medium risk:
  - substantial equivalence; special controls; premarket review
- High risk:
  - safety and effectiveness; premarket review

- Low risk:
  - essential requirements; self certification
- Medium risk:
  - essential requirements; 3rd-party review or corporate review
- High risk:
  - safety and performance data; 3rd-party premarket review

Study Group 1 Accomplishments:

- SG1 - N020R4: "Essential Principles of Safety and Performance of Medical Devices"
- Represents worldwide baseline for medical device requirements
- Endorsed at June 1999 meeting



Ongoing Activities of SG 1:

Working on several Proposed Documents:

-- role of standards in assessment of medical devices

-- recommendations on medical device classification (risk-based approach)

-- labeling for medical devices

-- summary Technical File (to demonstrate safety/performance, meet essential principles for Competent Authorities/Notified Bodies)

-- medical device definition(s)

Study Group 2 Mission:

The purpose of a vigilance and post-market surveillance system is to improve protection of health and safety of patients, users and others by reducing the likelihood of similar adverse incidents being repeated in different places at different times.

Basic Approach of SG 2:

- Initial focus on vigilance/AE reporting from manufacturer reporting to NCA
  -- regulatory comparisons
  -- minimum data set
  -- vigilance case definition & NCA-to-NCA reporting
  -- standardized reporting rules

Study Group 2 Accomplishments & Activities:

- 6 final documents endorsed in June 1999:

  -- charge and mission statement

  -- comparison of adverse report systems

  -- minimum data set for manufacturer reports to NCAs

  -- how to handle information concerning vigilance reporting

  -- global medical devices vigilance report

  -- adverse event reporting guidance for mfrs./authorized representative

Study Group 2
Accomplishments & Activities

- Future activities to focus on:
  -- competent authority reporting criteria
  -- terms and definitions
  -- worldwide vigilance exchange and a worldwide vigilance system

Study Group 3 Accomplishments & Activities:

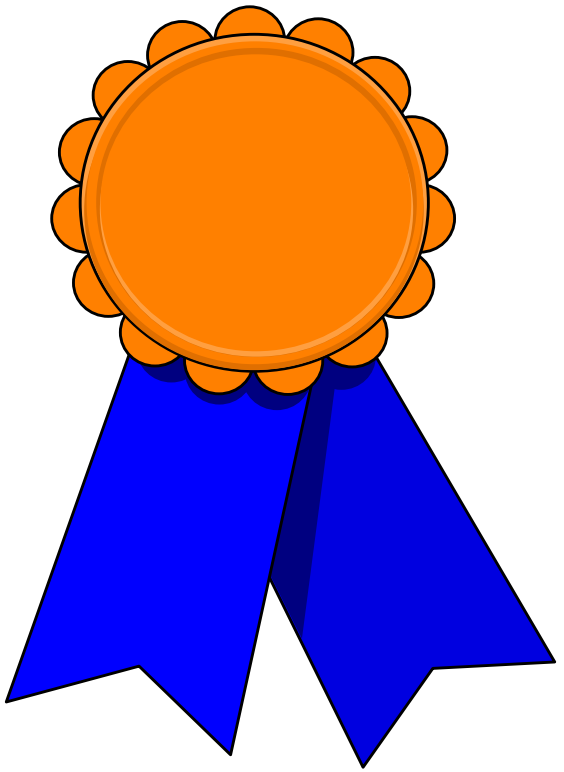
- Guidance on Quality Systems for Design and Manufacturing: done in 1994, endorsed in 1999
- Design Controls: endorsed in 1999
- Process Validation: endorsed in June 1999
- Quality Planning and Risk Management in process

Study Group 4 Accomplishments & Activities:

- General Requirements for Regulatory Auditing: endorsed in June 1999
- Audit Language Requirements (sub-set of General Requirements): endorsed in June 1999
- Audit duration, mutual recognition audits, training, observed audits for MRAs and auditing documentation under development

GHTF Accomplishments:

- **12 guidance documents endorsed**
- **EU requirements for quality systems and FDA GMPs nearly harmonized**
- **Joint audits by multiple countries ongoing**
- **Multiple post-marketing pilots underway**
- **Working agreement with ISO/TC 210**
- **New GHTF Web site (www.ghtf.org)**



Formalizing GHTF Procedures

- Major challenge to ensure process order and orderly expansion to accommodate emerging countries in the future
- US and EU drafts under consideration
- Ad Hoc Procedures Group, chaired by

  B. Pieterson/HealthCanada, to develop consensus procedures by GHTF meeting in 2000
- Key issues: countries vs. regions, degree of formality and specificity of procedures, processing of guidance documents

Chairmanship & Next Meeting:

- GHTF Chair rotates every 3 years: EU relinquished to North America in 1998: U.S. in role from 1998-99.
- Beth Pieterson, Acting Director, Medical Devices Bureau, Therapeutic Products Programme, Health Canada, serving as Chair effective Sept. 1, 1999 for next 12 months.
- Next meeting tentatively scheduled for Ottawa in Sept. 2000.

Liaison Relationship With ISO/ TC 210:

- Finalized an agreement in June 1999 to achieve multiple goals:
  -- promote communication
  -- avoid duplication
  -- provide formal, coordinated regulatory voice to TC 210 standards-setting activities
  -- promote “fit” of international standards
  -- utilize expertise of TC 210 to improve regulatory efficiency
  -- promote knowledge of GHTF to TC 210

Future Challenges:

- Urge national governments to adopt/implement endorsed GHTF guidance documents
- Organize GHTF for the future through development of consensus operating procedures
- Build greater participatory role for APEC, MERCOSUR and other interested parties
- Implement working agreement with TC 210
- Routinely ensure relevance/necessity for Study Group projects, institute strategic planning process
- Refine and promote wider use of GHTF Web site

What are the special challenges for regulators and industry?

- Understand differences in conceptual frameworks
- Continue to participate in international standards
- Pay attention to GHTF documents and pilot tests
- Gain international trust for all Study Group efforts